EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 October 2021
EMA/736192/2021
Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): dabigatran

Procedure No. EMEA/H/C/PSUSA/00000918/202103

Period covered by the PSUR: 18/03/2020 To: 18/03/2021

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for dabigatran, the scientific conclusions of CHMP are as follows:

In view of available data on spontaneous reports including several cases with a close temporal relationship and in view of a plausible mechanism of action, the PRAC considers that a causal relationship between dabigatran etexilate and anticoagulant-related nephropathy (ARN) is at least a reasonable possibility. The PRAC concludes that the product information of products containing dabigatran etexilate should be amended accordingly.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for dabigatran the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing dabigatran is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.